- 1 1. (Original) A water-soluble tablet comprising:
- 2 (a) at least one water-soluble active ingredient;
- 3 (b) one or more water soluble sugar alcohols;
- 4 (c) one or more water-soluble lubricants; and
- 5 (d) one or more pH modifiers,
- 6 wherein the tablet dissolves in less than about three minutes in less than about 30
- 7 ml of water to give a clear solution.
- 1 2. (Cancelled)
- 1 3. (Original) The tablet according to claim 1, wherein the tablet dissolves in
- 2 water within one minute to give a clear solution.
- 1 4. (Cancelled)
- 1 5. (Original) The tablet according to claim 1, wherein the tablet is dissolved in
- 2 less than about 15 ml of water.
- 1 6. (Original) The tablet according to claim 1, wherein the water-soluble active
- 2 ingredient has a solubility of at least 1 part in 30 parts of water at a neutral, acidic or
- 3 alkaline pH.
- 1 7. (Original) The tablet according to claim 1, wherein the therapeutic unit dose of
- 2 the active ingredient is soluble in about 30 ml of water in an acidic, alkaline or neutral pH.
- 1 8. (Cancelled)
- 1 9. (Original) The tablet according to claim 8, wherein the water-soluble active
- 2 ingredient comprises one or more of metformin hydrochloride, gabapentin, glibenclamide,
- 3 glipizide, diltiazem hydrochloride, verapamil hydrochloride, bupropion hydrochloride,
- 4 propranolol hydrochloride, dextromethorphan hydrobromide, diphenhydramine
- 5 hydrochloride, disopyramide hydrochloride, tramadol, fluoxetine hydrochloride,
- 6 paroxetine hydrochloride, pentoxifylline hydrochloride, and diclofenac sodium
- 1 10. 13. (Cancelled)

- 1 14. (Original) The tablet according to claim 1, wherein the one or more sugar
- 2 alcohols comprises one or more of sorbitol, mannitol, spray dried mannitol, xylitol,
- 3 erythritol isomalt, hydrogenated starch hydrolysates and combinations thereof.
- 1 15.–17. (Cancelled)
- 1 18. (Original) The tablet according to claim 1, wherein the one or more water-
- 2 soluble lubricants comprises one or more of DL-leucine, sodium lauryl sulphate,
- 3 magnesium lauryl sulphate and polyethylene glycol.
- 1 19.–21. (Cancelled)
- 1 22. (Original) The tablet according to claim 18, wherein the lubricant comprises
- 2 pulverized/micronised polyethylene glycol.
- 1 23. (Original) The tablet according to claim 22, wherein the polyethylene glycol
- 2 has particle size with 90% of the particles having a size less than 250  $\mu m$ .
- 1 24. (Original) The tablet according to claim 23, wherein the polyethylene glycol
- 2 has a molecular weight of from about 3,500 to about 20,000.
- 1 25. (Cancelled)
- 1 26. (Original) The tablet according to claim 1, wherein the pH modifier comprises
- 2 one or more of potassium hydroxide, sodium hydroxide, monosodium citrate, citric acid
- 3 and the like.
- 1 27. (Original) The tablet according to claim 1, wherein the tablet further comprises
- 2 one or more pharmaceutical excipients.
- 1 28.–30. (Cancelled)
- 1 31. (Original) The tablet according to claim 1, wherein the tablet comprises one or
- 2 more water-soluble active ingredients, xylitol, spray-dried mannitol and micronized
- 3 polyethylene glycol and the tablet dissolves in about 30 ml of water within three minutes
- 4 to give a clear solution.
- 1 32. (Original) A process for the preparation of a water-soluble tablet, the process
- 2 comprising compressing a mixture of:

- a. at least one water-soluble active ingredient;
- b. one or more water soluble sugar alcohols;
- 5 c. one or more water-soluble lubricants; and
- d. one or more pH modifiers,
- 7 wherein the tablet dissolves in about 3 minutes in about 30 ml of water to give a clear
- 8 solution.
- 1 33. (Cancelled)
- 1 34. (Original) The process according to claim 32, further comprising granulating
- 2 the mixture prior to compression.
- 1 35.– 36. (Cancelled)
- 1 37. (Original) The process according to claim 32, wherein the one or more water-
- 2 soluble active ingredients comprises metformin hydrochloride, gabapentin, glibenclamide,
- 3 glipizide, diltiazem hydrochloride, verapamil hydrochloride, bupropion hydrochloride,
- 4 propranolol hydrochloride, dextromethorphan hydrobromide, diphenhydramine
- 5 hydrochloride, disopyramide hydrochloride, tramadol, fluoxetine hydrochloride,
- 6 paroxetine hydrochloride, pentoxifylline hydrochloride, and diclofenac sodium.
- 1 38. (Original) The process according to claim 32, wherein the one or more water
- 2 soluble sugar alcohols comprises one or more of sorbitol, mannitol, spray dried mannitol,
- 3 xylitol, erythritol isomalt and hydrogenated starch hydrolysates and combinations thereof.
- 1 39. (Original) The process according to claim 32, wherein the one or more water-
- 2 soluble lubricants comprises one or more of DL-leucine, sodium lauryl sulphate,
- 3 magnesium lauryl sulphate and polyethylene glycol.
- 1 40. (Original) The process according to claim 32, wherein the one or more pH
- 2 modifiers comprises one or more of potassium hydroxide, sodium hydroxide, monosodium
- 3 citrate, and citric acid.
- 1 41. (Original) The process according to claim 32, wherein the mixture comprises
- 2 additional pharmaceutical excipients.
- 1 42.–44. (Cancelled)

- 1 45. (Original) A method of treating a condition, the method comprising
- 2 administering a water-soluble tablet comprising:
- a. at least one water-soluble active ingredient;
- b. one or more water soluble sugar alcohols;
- 5 c. one or more water-soluble lubricants; and
- d. one or more pH modifiers,
- wherein the tablet dissolves in less than about three minutes in less than about 30
- 8 ml of water to give a clear solution.
- 1 46. (Original) The method according to claim 45, wherein the one or more water-
- 2 soluble active ingredients comprises metformin hydrochloride, gabapentin, glibenclamide,
- 3 glipizide, diltiazem hydrochloride, verapamil hydrochloride, bupropion hydrochloride,
- 4 propranolol hydrochloride, dextromethorphan hydrobromide, diphenhydramine
- 5 hydrochloride, disopyramide hydrochloride, tramadol, fluoxetine hydrochloride,
- 6 paroxetine hydrochloride, pentoxifylline hydrochloride, and diclofenac sodium.
- 1 47.–49. (Cancelled)